

REMARKS

Applicants wish to thank Examiner Ramirez for discussing the Office Action dated May 1, 2007, with John Stolpa and Angela Dallas Sebor during a telephone interview on July 17, 2007. During this interview, the claim objections and issues under 35 U.S.C. § 112, First Paragraph, and 35 U.S.C. § 112, Second Paragraph, were discussed. The remarks below more accurately reflect the substance of the interview. Applicants have now amended all of the claims in the present application in a manner that is believed to place the claims in a condition for allowance. Accordingly, Applicants respectfully request that the Examiner enter this amendment and allow the pending claims.

Status of the Claims

Following this Amendment, claims 1, 4, 8-10, 12, 21, 25-41, 45-47, 49, 50, 52-54, 57-61, 219-226, 228-239 and 243-252 are now pending in the application. In the present Amendment, claims 2, 3, 7, 11, 13, 14, 17-20, 23, 55, 56, 207-212, 218, 227, and 240-242 have been canceled; claims 1, 4, 8, 9, 12, 21, 36-41, 45-47, 49, 52, 54, 57-59, 219, 222, 228, and 230-231 have been amended; and new claims 243-252 have been added. Support for these new and amended claims can be found throughout the specification and the originally filed claims. Applicants have not introduced any new matter by the amendments.

Specifically, support for microorganisms, including bacteria and yeast, can be found, *inter alia*, at page 63, line 16 to page 64, line 17.

Support for a glucosamine-6-phosphate acetyltransferase that is at least 95% identical to the amino acid sequence of SEQ ID NO:30 can be found, *inter alia*, at page 29, lines 5-27, and at page 68, lines 5-26.

Support for a glucosamine-6-phosphate synthases that are at least 95% identical to the amino acid sequences of SEQ ID NOs:4, 6, 8, 10, 12, 14, 16, 18 and 20 can be found at page 27, line 11, to page 29, line 4, and at page 68, lines 5-26.

Support for a method to produce N-acetylglucosamine-6-phosphate by fermentation can be found, *inter alia*, at page 39, lines 8-17; page 62, line 5 to page 63, line 3; and page 95, lines 11-23.

Support for a partial or complete deletion of a gene encoding ADP-glucose pyrophosphorylase, glycogen synthase, or a branching enzyme can be found, *inter alia*, at page 34, lines 1-3; page 41, line 21 to page 42, line 8; and page 48, lines 18-26.

Support for recovering an intracellular product selected from intracellular glucosamine-6-phosphate, glucosamine-1-phosphate, N-acetylglucosamine-6-phosphate, N-acetylglucosamine-1-phosphate, N-acetylglucosamine and glucosamine can be found, *inter alia*, at page 93, line 25 to page 94, line 16.

Support for purifying N-acetylglucosamine from fermentation medium can be found, *inter alia*, at Examples 34-42.

Support for dephosphorylating N-acetylglucosamine-6-phosphate to produce N-acetylglucosamine can be found, *inter alia*, at page 48, line 27 to page 49, line 14 and page 95, line 24 to page 96, line 13.

Support for treating N-acetylglucosamine to produce a glucosamine product selected from the group consisting of: glucosamine and glucosamine HCl can be found, *inter alia*, at Examples 43-58.

Support for hydrolyzing N-acetylglucosamine under acid and heat conditions or by enzymatic deacetylation can be found, *inter alia*, at Examples 43-47.

Support for contacting the fermentation medium with at least one ion exchange resin can be found, *inter alia*, at page 97, line 16 to page 98, line 16 and Examples 37-39.

Claim Objections

Claims 7-8 and 17-18 were objected to as being directed, in part, to non-elected subject matter. Applicants have canceled claims 7, 17, and 18. Applicants have also amended claim 8 to remove non-elected sequences SEQ ID NO:32 and SEQ ID NO:34. Thus, all pending claims now recite only elected subject matter.

Claim 218 was objected to due to the recitation of "a the bacterial or yeast...." Claim 218 has been amended to remove the term "the" as suggested by the Examiner.

Claims 223, 224 and 229 were objected to due to the recitation of "partial or complete deletion of [gene name]." Claims 223, 224 and 229 have been amended to

recite “partial or complete deletion of the [gene name] gene”, as suggested by the Examiner.

The claims were objected to due to the recitation in claims 1, 218, 219, 222 and 240 of a method to make glucosamine and N-acetylglucosamine in the preamble, yet a step of collecting products distinct from glucosamine and N-acetylglucosamine (for example, glucosamine-1-phosphate). Claims 218 and 240 have been canceled. Claims 1, 219 and 222 have been amended to clarify that the recited methods produce N-acetylglucosamine and N-acetylglucosamine-6-phosphate. Claims 1, 219 and 222 have also been amended to recite a step of collecting only N-acetylglucosamine and N-acetylglucosamine-6-phosphate.

Claim 57 recites an additional step of recovering an intracellular product selected from intracellular glucosamine-6-phosphate, glucosamine-1-phosphate, N-acetylglucosamine-6-phosphate, N-acetylglucosamine-1-phosphate, N-acetylglucosamine and glucosamine. As discussed with the Examiner, the specification makes clear that these products, while not the predominant products resulting from practicing the claimed methods, are produced by the microorganisms recited in the claims. Thus, these products may be recovered after the fermentation process, in addition to the desired products of N-acetylglucosamine and N-acetylglucosamine-6-phosphate. Thus, Applicants submit that the recovery of these additional products is possible even though the method is predominately directed to the production of N-acetylglucosamine and N-acetylglucosamine-6-phosphate.

In view of these claim amendments and cancellations, Applicants respectfully request that all claim objections be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 7, 17, 219, 228 and 230-239 were rejected under 35 U.S.C. § 112, Second Paragraph, as being indefinite for directly or indirectly reciting terms such as “wherein the glucosamine-6-phosphate acetyltransferase has acetyltransferase activity.” Claims 7 and 17 have been canceled.

Applicants agree with the Examiner that the enzymatic activity of the recited polypeptides is indicated by the recitation of the enzyme’s functional name earlier in the

claims. Therefore, claim 219 (claims 228 and 230-239 dependent thereon) has been amended to remove the terms "has glucosamine-6-phosphate synthase enzymatic activity" and "has glucosamine-6-phosphate acetyltransferase enzymatic activity," as suggested by the Examiner.

Claim 47, 227-228 and 230-233 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "a partial or complete deletion of [protein name]." Claim 227 has been canceled. As suggested, by the Examiner, claims 47, 228 and 230-231 (claims 232-233 dependent thereon) have been amended to recite the language "a partial or complete deletion of an endogenous gene encoding [protein name]." Claim 54 has been amended in a similar manner for clarity.

Accordingly, in light of the amendments discussed above, Applicants respectfully request that all rejections under 35 U.S.C. § 112, Second Paragraph, be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description

Claims 1-4, 9-14, 17-21, 23, 25-41, 45-47, 49-50, 52-61, 207-212, 218, 227 and 240-242 were rejected under 35 U.S.C. § 112, First Paragraph, as failing to comply with the written description requirement. According to the Office, these claims encompass, but the specification does not support, a genus of modifications that would increase or decrease the activity of a genus of enzymes and a genus of nucleic acids encoding a genus of bacterial or yeast proteins. Office Action, page 7.

Applicants respectfully traverse this rejection and respectfully submit that the specification provides adequate written description support for all pending claims. However, in an effort to expedite prosecution, Applicants have canceled claims 2, 3, 11, 13, 14, 17-20, 23, 55, 56, 207-212, 218, 227, and 240-242 without prejudice. Applicants have further amended claims 1, 4, 9, 12, 21, 36-41, 45-47, 49, 50, 52, 54 and 57-59.

As discussed with the Examiner, all pending claims now recite nucleic acid molecules that are at least 95% identical to nucleic acid molecules expressly disclosed in the specification. Further, the structural modifications recited in the instant claims are limited to the partial or complete deletion of genes disclosed in the specification.

Therefore, in view of the amendments, Applicants respectfully submit that the specification provides adequate written description support for all pending claims. Accordingly, Applicants request that all rejections under 35 U.S.C. § 112, First Paragraph, be withdrawn.

Enablement

Claims 1-4, 9-14, 17-21, 23, 25-41, 45-47, 49-50, 52-61, 207-212, 218, 227 and 240-242 were rejected under 35 U.S.C. § 112, First Paragraph, as failing to comply with the enablement requirement. According to the Office, the specification does not provide enabling support for culturing a microorganism that has a genus of modifications that would increase or decrease the activity of a genus of enzymes or a genus of nucleic acids encoding a genus of bacterial or yeast proteins.

Applicants respectfully traverse this rejection and respectfully submit that the specification provides adequate enabling support for all pending claims. However, in an effort to expedite prosecution, Applicants have canceled claims 2, 3, 11, 13, 14, 17-20, 23, 55, 56, 207-212, 218, 227, and 240-242 without prejudice. Applicants have further amended claims 1, 4, 9, 12, 21, 36-41, 45-47, 49, 50, 52, 54 and 57-59.

As discussed above, all pending claims now recite nucleic acid molecules that are at least 95% identical to nucleic acid molecules expressly disclosed in the specification. Further, the structural modifications recited in the instant claims are limited to the partial or complete deletion of genes disclosed in the specification.

Combining the teachings of the specification with the knowledge in the art at the priority date of the application, one of skill in the art could readily make and use the full scope of the invention recited in the pending claims without undue experimentation. Therefore, the enablement requirement of 35 U.S.C. § 112, First Paragraph, has been satisfied. Applicants thus respectfully request that these rejections be withdrawn.

Rejoinder

In an Office Action dated March 22, 2006, the Examiner required the election of one glucosamine-6-phosphate synthase selected from SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 18, and 20. Subsequently, in an Office Action dated August 10, 2006, the Examiner considered Applicants arguments concerning the restriction requirement and

agreed to examine the synthases denoted SEQ ID NOS: 2, 4, 6, 8, 10, 12, and 14 in the instant application.

Applicants respectfully request that the Examiner rejoin the synthases denoted SEQ ID NOS: 16, 18 and 20 to the pending claims. As discussed in the interview, the instant claims, as amended, are considered allowable based on the expression of the glucosamine-6-phosphate acetyltransferase denoted SEQ ID NO:30. The synthases denoted SEQ ID NOS: 16, 18 and 20 are only recited in claims 219 and 243-245, each of which also recites the expression of the glucosamine-6-phosphate acetyltransferase denoted SEQ ID NO:30.

Applicants submit that the inclusion of the additional synthases will not change the allowability of claims 219 and 243-245, and will not require that an additional search be conducted by the Examiner. Therefore, Applicants respectfully request that the Examiner rejoin the synthases denoted SEQ ID NOS: 16, 18 and 20 to claim 219 and find claims 219 and 243-245 allowable as amended.

Conclusions

In view of the foregoing amendments and remarks, Applicants respectfully request that the Examiner enter the amendments contained in this paper and timely allow all of the pending claims. If the Examiner has any questions regarding this Amendment and Response, she is invited to contact the undersigned at 303-863-9700.

The required one-month extension of time fee of \$120.00 is submitted herewith via EFS-Web. In the event that additional fees are due in connection with this response, please debit Deposit Account No. 19-1970.

Respectfully submitted,

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